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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT PAPER NUMBER

3733

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/712,202

Applicant(s)

HUEBNER ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-9, 11, 13-15 and 17-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-9, 11, 13-15 and 17-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-9, 13-15, 17, 18, 20, 27-37, 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by DiPoto et al. (US Pat. 5,957,953).

DiPoto et al. disclose a bone screw for compression of a bone, comprising: a shank (Fig. 9A, ref. 204) including a thread (Fig. 9, ref. 206) and defining a long axis (Fig. 9, the axis extending from the end near ref. 206 to the end near ref. 200) and a direction of advancement into bone (Fig. 9, the direction extending from the end near ref. 200 towards the end near ref. 206); and a head (Fig. 9, the entire second portion near ref. 230) connected to the shank (as in Fig. 9b) and defining a plurality of ledge structures (Fig. 9A, ref. 228) disposed at spaced positions along the head (Fig. 9A), each ledge structure facing generally toward the direction of advancement (Fig. 9A, ref. 228, since they are angled in that direction) and extending partially (Fig. 9A) or completely around the head to define a respective plane disposed orthogonally to the long axis (Fig. 9A). The shank has a proximal portion (Fig. 9, near ref. 208) adjacent the head and a distal portion (Fig. 9, near ref. 206) spaced from the head (column 9, lines 14-19 since there is room enough to allow them to rotate relative to each other when they are being screwed together) and wherein the thread is restricted to the distal

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portion (Fig. 9). The thread defines an opening so that the bone screw is self-tapping (column 8, lines 21-23). The shank includes a tip region (Fig. 9, the narrowed portion at the end of ref. 206) configured to cut a hole in the bone as the bone screw is advanced into the bone. The ledge structures are formed by a plurality of ridges (Fig. 9A, edge near ref. 228), a plurality of grooves (Fig. 9A, ref. 216), or both. The diameter of the plurality of ledge structures have a corresponding plurality of diameters, and wherein the diameters decrease successively toward the shank (Fig. 3B, refs. 24). The head is shaped generally as a frustum of a cone (Fig. 9, ref. 222). The head includes a plurality of steps defined by stepwise decreases in the diameter of the head (Fig. 3B, decreasing diameters of refs. 24), and wherein the plurality of ledge structures are included in the plurality of steps. The shank and the head define opposing ends of the bone screw (Fig. 9B, refs. 208 and near ref. 224) and further define an axial bore (Fig. 9, ref. 218) extending between the opposing ends. The axial bore includes a widened region (Fig. 9B, widened portion near ref. 206) configured to receive a tool that engages the head. The head is rotatably and/or slidably connected to the shank since the shank can slide into and out of the head, as in Figs. 9 and 9B.

A bone screw for compression of a bone, comprising: a shank (Fig. 9A, ref. 204) including a thread (Fig. 9, ref. 206) and defining a long axis (Fig. 9, the axis extending from the end near ref. 206 to the end near ref. 200); and a head (Fig. 9, the entire second portion near ref. 230) connected rotatably (column 9, lines 15-17, since they rotate as they are screwed together) to the shank and configured to follow the shank into the bone, the head having an aspect ratio defined by its axial length relative to its

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maximum diameter, the aspect ratio being at least 1:1, wherein the axial length is measured parallel to the long axis (Fig. 9).

A bone screw for compression of a bone, comprising: a shank (Fig. 9A, ref. 204) including a thread (Fig. 9, ref. 206) and defining a long axis (Fig. 9, the axis extending from the end near ref. 206 to the end near ref. 200) and a direction of advancement into bone (Fig. 9, the direction extending from the end near ref. 200 towards the end near ref. 206); and a head (Fig. 9, the entire second portion near ref. 230) connected to the shank and including a plurality of spaced shoulders (Fig. 9A, ref. 228) of different diameter, each shoulder facing generally in the direction of advancement (since they are tapered in that direction) and extending partially (Fig. 9A) or completely around the long axis in a respective path defining a plane (Fig. 9A). The different shoulders can be considered to have different diameters, since they are sloped (Fig. 9). Due to the slope, each shoulder has multiple diameters depending on where along the sloped edge the diameters are taken. Measuring the diameter of each shoulder at a different point along the sloped portion would yield different diameters for each shoulder. Each shoulder follows a respective path defining a plane oriented orthogonally to the long axis (Fig. 9A). Each shoulder follows a respective path corresponding to one or more portions of a circle (Fig. 9A) or a complete circle. Each shoulder slopes radially outward, generally toward the direction of advancement into bone (when expanded, as in Fig. 3B). The head includes at least one generally cylindrical segment (Fig. 9A, ref. 216) disposed at least partially between a pair of the shoulders.

With regard to the statements of intended use and other functional statements (e.g. ...configured to exert an axial force..., ...configured to apply a greater axial force..., ...configured to receive a tool..., ...configured to cut a hole...), they do not impose any structural limitations on the claims distinguishable over the screw of Schenk, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

DiPoto et al. disclose a method of compressing a bone with a bone screw, comprising: forming a hole in the bone (column 7, lines 61-62); selecting a bone screw having a shank (Fig. 4, ref. 79) and a head (Fig. 4, ref. 70); and advancing first the shank (column 7, lines 61-62) (Fig. 5, since ref. 79a projects from the head member) and then the head of the bone screw into the hole (column 7, lines 61-62) so that the head contacts and applies an axial force selectively to a plurality of spaced annular regions of the bone (the portions of the bone near refs. 74) that each define a respective plane, such that portions of the bone near the head are compressed toward portions of the bone near the shank. The spaced annular regions being separated by interposed regions of the bone (once the screw is inserted into the bone, column 7, lines 61-62),

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wherein the step of advancing also applies an axial force to the interposed regions, the axial force applied to the interposed regions being less than the axial force applied to the plurality of spaced annular regions. The spaced annular regions being separated by interposed regions of the bone (once the screw is inserted into the bone, column 7, lines 61-62), wherein the step of advancing also applies no substantial axial force to the interposed regions. The step of forming a hole includes forming a bore (Fig. 3, the bottom tip of ref. 44), and a counterbore (Fig. 3, the upper, wider portion of ref. 44), and wherein the step of advancing the bone screw disposes the head and the shank at least substantially in the counterbore (Fig. 3, ref. 26 in counterbore) and the bore (Fig. 44, ref. 79a would fit into the bottom tip of ref. 44), respectively. The step of forming a hole is performed by the step of advancing a bone screw (column 8, lines 20-22). The portions of the bone near the head and the portions of the bone near the shank are initially separated by a fracture in the bone, since a hole is drilled into the bone (Fig. 3, ref. 44). One or more of the ledge structures slopes radially outward, generally toward the direction of advancement into bone (Fig. 3B, ref. 24).

Claims 21-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Schenk (US Pat. 6,048,344).

A bone screw for compression of a bone, comprising: a shank (top Fig. 4, below) including a proximal region (top Fig. 4, below), a distal region (top Fig. 4, below), and a thread (Fig. 4, ref. 61) restricted to the distal region; and a head (top Fig. 4, below), connected to the shank and spaced from the thread by the proximal region (Fig. 4,

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below), the head including a lateral surface defining a plurality of spaced ledge structures (bottom Fig. 4, below) disposed on the head, each ledge structure describing at least a portion of a circle. Each ledge structure describes at least a portion of a circle, since a circle consists of an infinite number of points that are spaced an equal distance from a radius. The ledge structures all comprise at least one point, which can be considered to be a portion of a circle. The ledge structures are defined by a plurality of ridges (bottom Fig. 4, below), a plurality of grooves, or both. The ledge structures describe complete circles, since, as viewed from a top-down perspective along the long axis, the ledge structures appear to form a circle. The head includes a plurality of steps defined by stepwise decreases in the diameter of the head (top Fig. 4 below, as shown with the added narrowing lines), and wherein the plurality of ledge structures are included in the plurality of steps (bottom Fig. 4, below). The head is generally frustoconical in shape (top Fig. 4, below). The shank defines a long axis (Fig. 4, the axis from ref. 69-70), wherein the head has a maximum diameter, wherein the head has an axial length that is measured parallel to the long axis, wherein the head has an aspect ratio defined by the axial length of the head relative to the maximum diameter of the head, and wherein the aspect ratio is at least 1:1 (column 4, lines 11-15).

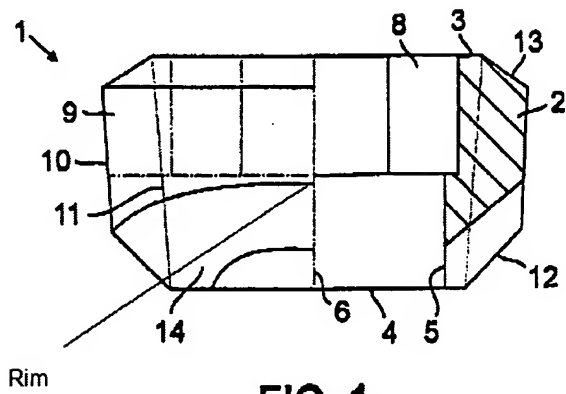
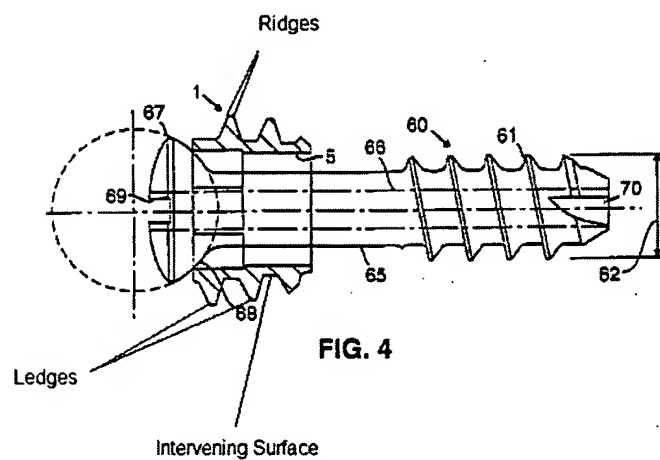
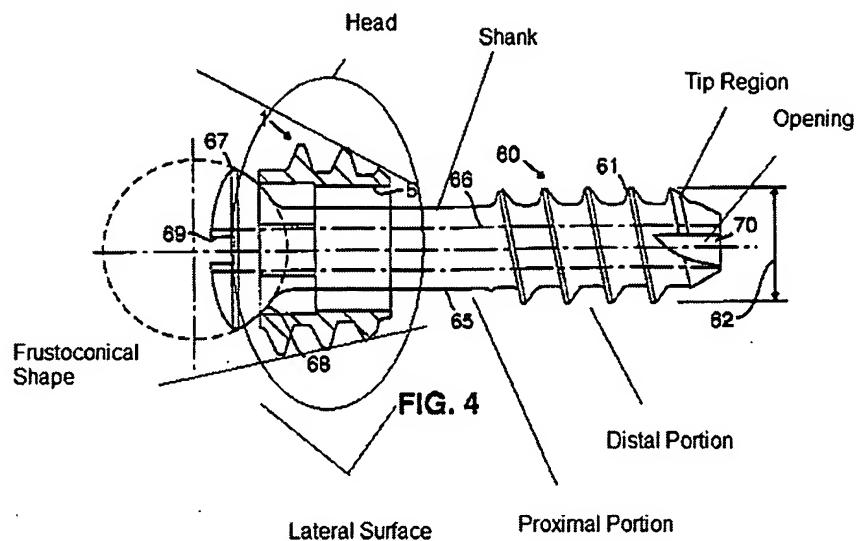


FIG. 1



Claim Rejections - 35 USC § 103

Claims 5-9, 13-15, 17-20, 27-37, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiPoto et al. (US Pat. 5,957,953).

With regards to claim 19, DiPoto et al. disclose the claimed invention except for the head being fixedly connected to the shank. It would have been obvious to one having ordinary skill in the art at the time the invention was made to fixedly attach the head to the shank, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Claims 5-9, 11, 13-15, 17-20 and 27-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiPoto et al. (US Pat. 5,957,953) in view of Bowman (US Pub. 2002/0095157 A1).

DiPoto et al. disclose the claimed invention except for the at least one or more of the plurality of ledge structures extending in a closed loop corresponding to a circle and each shoulder extending completely around the long axis in a closed loop.

Bowman discloses at least one or more of a plurality of ledge structures (Fig. 1, ref. 40) extending in a closed loop corresponding to a circle (Fig. 1) and each shoulder (Fig. 1, ref. 44) extending completely around the long axis in a closed loop (Fig. 1), which are used to prevent the device from withdrawing from a bone (paragraph 0011, last line).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the ledge structures of DiPoto et al. extending in a closed loop corresponding to a circle and each shoulder extending completely around the long axis in a closed loop of Bowman, in order to prevent the

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device of DiPoto et al. from withdrawing from a bone (Bowman, paragraph 0011, last line).

Response to Arguments

Applicant's arguments with respect to claims 5, 6-9, 11, 13-15, 17-20 and 27-40 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to claims 21-26 have been fully considered, but are not persuasive.

With regards to Applicant's argument that Schenk does not teach or suggest each ledge structure describing at least a portion of a circle, the examiner respectfully disagrees. Each ledge structure describes at least a portion of a circle, since a circle consists of an infinite number of points that are spaced an equal distance from a radius. The ledge structures all comprise at least one point, which can be considered to be a portion of a circle.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

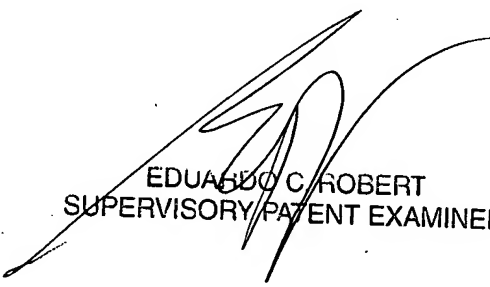
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER